

<sup>1</sup> Glyphosate is a broad-spectrum herbicide, originally patented and sold by Monsanto under the Roundup® name.

Ready® (“RR”) glyphosate-tolerant soybean and corn traits they licensed from Monsanto; (2) Defendants are precluded from introducing extrinsic evidence, allegedly indicating that the parties intended the license agreements to permit the aforementioned stacking, due to the unambiguous nature of the field of use restrictions in the agreements; and (3) the license agreements contain implied negative prohibitions on stacking, which Defendants breached – assuming that the agreements and the underlying patents are otherwise enforceable – by stacking OGAT with the licensed RR traits. *See Monsanto Co. v. E.I. DuPont de Nemours & Co.*, 2010 WL 234951 (E.D. Mo. 2010). Defendants now bring this Motion for Reconsideration directed at those conclusions.

“Motions for reconsideration are nothing more than Rule 60(b) motions when directed at non-final orders.” *Elder-Keep v. Aksamit*, 460 F.3d 979, 984 (8th Cir. 2006) (internal quotations and citations omitted). Rule 60(b) provides that a court may reconsider a prior ruling for one of the following reasons:

- (1) mistake, inadvertence, surprise, or excusable neglect;
- (2) newly discovered evidence that, with reasonable diligence, could not have been discovered in time to move for a new trial under Rule 59(b);
- (3) fraud (whether previously called intrinsic or extrinsic), misrepresentation, or misconduct by an opposing party;
- (4) the judgment is void;
- (5) the judgment has been satisfied, released or discharged; it is based on an earlier judgment that has been reversed or vacated; or applying it prospectively is no longer equitable; or
- (6) any other reason that justifies relief.

Rule 60(b) relief is an “extraordinary remedy” that is justified only in “exceptional circumstances,” *Prudential Ins. Co. of America v. Nat’l Park Med. Ctr., Inc.*, 413 F.3d 897, 903 (8th Cir. 2005), and “[e]xceptional circumstances are not present every time a party is subject to

potentially unfavorable consequences as a result of an adverse judgment properly arrived at.”

*Atkinson v. Prudential Prop. Co.*, 43 F.3d 367, 373 (8th Cir. 1994) (internal quotations omitted).

In the context of a motion under Rule 60(b)(6) – the catch-all provision applicable to Defendants’ Motion – relief will only be granted where the “exceptional circumstances have denied the moving party a full and fair opportunity to litigate his claim and have prevented the moving party from receiving adequate redress.” *See Harley v. Zoesch*, 413 F.3d 866, 871 (8th Cir. 2005). As such, a Rule 60(b)(6) motion that does nothing more than attempt to reargue issues already decided should be denied. *Broadway v. Norris*, 193 F.3d 987, 989-90 (8th Cir. 1999) (“In their ‘motion for reconsideration,’ defendants did nothing more than reargue, somewhat more fully, the merits of their claim of qualified immunity. This is not the purpose of Rule 60(b)(6). . . . It is not a vehicle for simple reargument on the merits.”).

Defendants first argue that the Court erred in finding the license agreements unambiguous in not granting them a license to stack glyphosate-tolerant traits, in that Defendants offered extrinsic evidence demonstrating that the supposed restrictions on stacking are latently ambiguous. The provision defining the phrase “Licensed Field” – the field in which Defendants, as the licensees, are permitted to use the licensed RR traits – states that it is “Licensed Commercial Seed which exhibit genetically-engineered protection against Glyphosate herbicide *solely* due to the presence of the [RR soybean or corn traits].” (emphasis added). Defendants claim that the term “solely” is latently ambiguous because it could also be read as limiting Monsanto’s license grant “solely” to the RR traits, and not to other patented Monsanto technologies conferring glyphosate tolerance. Defendants contend that this latent ambiguity becomes evident when one considers their proffered extrinsic evidence: a letter of intent indicating that the parties did not, at that time at least, intend for the agreements to prohibit stacking, and

the Yieldgard® license, which the parties agreed to on the same day as these license agreements and which contains an express prohibition on stacking.

This is little more than an attempt to reargue issues the parties fully briefed and argued to the Court, and as such Defendants' Motion could be denied solely on that basis; in any event, however, Defendants fail to establish that the Court's conclusion was in error. Defendants' interpretation of the clause does not suggest a latent ambiguity, but instead suggests a reading of the clause that contradicts its plain language. In order for Defendants' interpretation to be plausible, it must be possible to read the "Licensed Field" provision as permitting Defendants to stack glyphosate-tolerant traits. An OGAT/RR stacked seed product, however, would not "exhibit genetically-engineered protection against Glyphosate herbicide solely due to the presence of" a RR trait; it plainly would exhibit glyphosate tolerance due to both traits, being that both are introduced for the purpose of imparting glyphosate tolerance. As the Court explained in its January 15 Order:

The principal problem with [Defendants'] interpretation is that it effectively reads the word "solely" out of subparagraph 2.11. If 2.11 stated that the Licensed Field is "Licensed Commercial Seed which exhibit genetically-engineered protection against Glyphosate herbicide *due to* the presence of [the RR soybean or corn trait]," it might be reasonable to read it [alternatively] as preventing the grant from extending to other Monsanto technology covered by the '247 patent, and as such, as unrelated to Pioneer's ability to stack other glyphosate-tolerant traits.

*Monsanto Co. v. E.I. DuPont de Nemours & Co.*, 2010 WL 234951, at \*4 (E.D. Mo. 2010). The field of use restriction, however, states that Defendants can only use the RR soybean and corn traits in seed products that exhibit glyphosate tolerance "solely due to" these RR traits; this necessarily means that the licenses do not extend to using the RR traits in combination with other glyphosate-tolerant traits, regardless of whether the non-RR glyphosate-tolerant trait is OGAT or another Monsanto-patented trait.

Thus, although there is Delaware authority suggesting that courts may consider undisputed extrinsic evidence of negotiations and contracting circumstances to determine whether a contract provision is latently ambiguous, *see, e.g., Concord Steel, Inc. v. Wilmington Steel Processing Co.*, 2009 WL 3161643, at \*6 (Del. Ch. 2009); *Cephalon, Inc. v. Johns Hopkins Univ.*, 2009 WL 4896227, at \*11 (Del. Ch. 2009), that case law is not relevant here because there is no real claim that the agreements are latently ambiguous. As such, Defendants would not be entitled to present this evidence, even if the Court were to assume that this case does present the rare situation in which a court may consider extrinsic evidence to interpret an unambiguous contract. *See Eagle Indus, Inc. v. DeVilbiss Health Care, Inc.*, 702 A.2d 1228, 1233 n.7, 1232-33 (Del. 1997) (suggesting, without deciding, that “[t]here may be occasions where it is appropriate for the trial court to consider some undisputed background facts to place the contractual provision in its historical setting without violating” the principle that “[i]f a contract is unambiguous, extrinsic evidence may not be used to interpret the intent of the parties, to vary the terms of the contract or to create an ambiguity.”). The Court therefore concludes that Defendants’ Motion will be denied on this point.

Defendants next claim that the Court erred in implying a negative covenant in the license agreements in the context of a motion for judgment on the pleadings. In support of their argument, Defendants offer a significant amount of Delaware authority indicating that implying contract terms requires scrutiny of the parties’ intentions and the circumstances of the agreement. *See, e.g., Cincinnati SMSA Ltd. P’Ship v. Cincinnati Bell Cellular Sys. Co.*, 708 A.2d 989, 992 (Del. 1998) (obligations that “can be understood from the text of the written agreement but have nevertheless been omitted in the literal sense” may be implied as a matter of good faith and fair dealing but “those cases should be rare and fact-intensive, turning on issues of compelling

fairness”); *Dunlap v. State Farm Fire & Cas. Co.*, 878 A.2d 434, 442 (Del. 2005) (“This Court has recognized the occasional necessity of implying contract terms to ensure the parties’ reasonable expectations are fulfilled. This quasi-reformation, however, should be a rare and fact-intensive exercise, governed solely by issues of compelling fairness.”) (internal quotations, alterations, and citations omitted); *see also McIlquham v. Feste*, 2001 WL 1497179, at \*6 (Del. Ch. 2001); *Moore Bus. Forms, Inc. v. Cordant Holdings Corp.*, 1995 WL 662685, at \*8-\*9 (Del. Ch. 1995). One means of pursuing this inquiry is to ask whether the parties, if they had addressed the subject, would have agreed to create the obligation at issue. *E.I. DuPont de Nemours & Co. v. Pressman*, 679 A.2d 436, 443 (Del. 1996) (internal citations omitted); *see also Katz v. Oak Indus. Inc.*, 508 A.2d 873, 880 (Del. Ch. 1986); *Schwartzberg v. CRITEF Assocs. Ltd. P’ship*, 685 A.2d 365, 376 (Del. Ch. 1996).

The Court agrees with Defendants that the fact-intensive nature of this inquiry, in the context of Monsanto’s breach of contract claim, requires a more fully developed factual record, one that includes consideration of the offered extrinsic evidence. Defendants contend that the letter of intent and the Yieldgard® license are highly relevant to their understandings and expectations in entering into the agreements, and under the cases cited above, they are entitled to present this evidence in support of their argument that the license agreements should not be read to contain an implied prohibition on stacking glyphosate-tolerant traits. That said, the Court cautions that it does not believe this evidence to be especially probative of the intentions of highly sophisticated contracting parties. The inquiry into implying a contractual obligation is fact-intensive and case-specific, and as the Court explained in the January 15 Order, the Court believes that in the circumstances of this case, the most relevant facts, in determining whether to imply a negative prohibition on stacking glyphosate-tolerant traits, are the presence of the unambiguous

field of use restriction, accompanied by violations of that restriction that were directly facilitated by Monsanto's performance of its obligations under the license agreements.

Related to that point, and much more significant to the Court's decision to reconsider its finding of an implied negative covenant, is Defendants' claim that the January 15 Order was based on an incorrect factual premise: that Monsanto's obligations under the license agreements to deliver biological materials and proprietary technical information to Defendants enabled Defendants to create the OGAT/RR stacked seed products. This, as noted above, was a critical assumption underlying the Court's rationale in implying a negative covenant:

The Monsanto-Pioneer agreements involve the presence of the two factors that have led courts and commentators to find implied negative covenants: a restriction on the field of use – the prohibition on stacking glyphosate-tolerant traits . . . – and a grant of technical information – Monsanto's delivery of biological materials and confidential proprietary information to [Defendants]. [Defendants] would have presumably been unable to infringe on the '247 Patent in the manner alleged here – that is, by stacking OGAT with the [licensed RR traits] – had Monsanto not supplied it with the necessary biological materials and related proprietary technical information . . . . These circumstances demonstrate that instead of leaving Pioneer in the shoes of the average infringer, which is how [Defendants claim they] should be treated in asserting that Monsanto's sole remedy is a suit for patent infringement, the nature of the agreements – and Monsanto's performance of its corresponding obligations – enabled Pioneer to stack the [RR traits] with OGAT, such that its appropriate to recognize an implied negative covenant on the part of [Defendants] not to do so.

Defendants assert that they could have produced OGAT/RR stacked seeds without accepting the benefits of Monsanto's obligations under the agreements – that is, that the license agreements did not facilitate their alleged infringement of Monsanto's patents. The Court's rationale in implying a negative covenant would be severely undercut if Defendants' claims are factually accurate, and this is obviously a factual matter that cannot be resolved on a motion for judgment on the pleadings. As such, Defendants will be given the opportunity to present evidence supporting their

claims before the Court reaches a final determination as to whether to imply a prohibition on stacking glyphosate-tolerant traits in the license agreements.

In sum, then, Defendants' Motion for Reconsideration will be granted in part, and denied in part. The Court will not reconsider its ruling that the license agreements did not grant Defendants a right to create OGAT/RR stacked seed products, because contrary to Defendants' claims, the field of use restriction, limiting Defendants' use of the licensed RR traits to "Licensed Commercial Seed which exhibit genetically-engineered protection against Glyphosate herbicide solely due to the presence of the [RR soybean or corn trait]," cannot plausibly be read to permit the stacking of glyphosate-tolerant traits. The Court agrees with Defendants, however, that it was error to imply a negative prohibition on stacking in the absence of a more developed factual record on Monsanto's breach of contract claim, and the January 15 Order will therefore be vacated to the extent it implied a negative covenant in the license agreements and found that Defendants breached that covenant by producing OGAT/RR stacked seed products. It necessarily follows that the Court will also vacate the dismissal of Defendants' Counterclaim XI, for a declaratory judgment that they did not breach the soybean and corn license agreements.

## **II. MOTION FOR CERTIFICATION OF QUESTIONS**

Defendants ask the Court to certify three questions of law – essentially the same issues that were the subject of their Motion for Reconsideration – to the Delaware Supreme Court:

- (1) Before deciding that, as a matter of law, a contract is unambiguous does the Court need to allow discovery and consider proffered evidence of the parties' negotiations in order to gain an understanding of the context and business circumstances under which the language was negotiated which shows seemingly unequivocal language was latently ambiguous?
- (2) Before deciding that, as a matter of law, a patent license agreement contains an implied negative covenant by the licensee, where the license contains no express negative covenant, does the Court need to allow discovery and consider proffered evidence of the other facts and



circumstances surrounding the parties' negotiations of the license that show the parties agreed not to include such a negative covenant?

- (3) Does a license agreement for the use of patented technology in a limited field contain, as a matter of law, an implied negative covenant by the licensee not to use the patented technology outside the licensed field where no express covenant exists, but where the license provides for the delivery of proprietary technical information and materials related to the patented technology by the licensor to the licensee?

Monsanto contends that certification is inappropriate here because the Court has already ruled on these questions, and because these issues are not novel or accompanied by important or urgent reasons as to why certification is necessary.

Federal courts may resort to state certification procedures when presented with “novel, unsettled questions of state law,” *Arizonans for Official English v. Arizona*, 520 U.S. 43, 79 (1997), but certification is to be discouraged – and is generally refused – where the parties have already presented the issue for decision to the district court. *See Rural Water Sys. No. 1 v. City of Sioux Center*, 202 F.3d 1035, 1037 n.6 (8th Cir. 2000) (refusing to certify statutory interpretation question to Iowa Supreme Court where defendant made motion for certification after district court construed statute); *Perkins v. Clark Equip. Co., Melrose Div.*, 823 F.2d 207, 209 (8th Cir. 1987) (“Once a question is submitted for decision in the district court, the parties should be bound by the outcome unless other grounds for reversal are present. Only in limited circumstances should certification be granted after a case has been decided.”); *Greika v. United States*, 281 Fed. App’x 631, 633 (8th Cir. 2008) (declining to certify question to Arkansas Supreme Court where certification first requested on appeal). Here, Defendants did not seek to have these questions certified to the Delaware Supreme Court until after this Court ruled in favor of Monsanto on its Motion for Partial Judgment on the Pleadings, specifically deciding the questions Defendants seek to certify adversely to Defendants’ position. There would be no

benefit in terms of simplifying the ultimate adjudication of this case, as the issues that would be submitted to the Delaware Supreme Court have already been subjected to a full round of briefing before this Court and are the subject of the Court's January 15, 2010 Memorandum and Order. Although this Court has determined, as discussed above, that a certain portion of that decision will be reconsidered, it remains the case that the Court has already fully considered and decided the issues for which certification is sought.

Under the Delaware procedural rules governing certified questions, moreover, a court from another jurisdiction may only certify a question to the Delaware Supreme Court if "the certifying court or entity has not decided the question or questions in the matter." Del. Supreme Ct. R. 41(a)(ii). Defendants claim that this only refers to situations in which there is applicable, pre-existing decisional law that is binding on the certifying court, for example due to a prior decision, but this interpretation does violence to the language of the Rule. This Court *is* "the certifying court," and it *has* "decided the question or questions in the matter." The plain language of the Rule could not be any clearer, and Defendants have failed to point to any case in which the Delaware Supreme Court accepted a certified question in circumstances similar to those presented here.

As such, the Court concludes that Defendants' Motion to certify these questions to the Delaware Supreme Court will be denied because they failed to seek certification before the Court considered and decided the questions at issue, making certification inappropriate as a matter of both federal and Delaware law.

### **III. MOTION FOR LEAVE TO FILE SECOND AMENDED ANSWER AND COUNTERCLAIMS**

Federal Rule of Civil Procedure 15(a) governs pre-trial amendments of pleadings, and where, as here, a party is not entitled to amend “as a matter of course” – as defined in the Rule – “a party may amend its pleading only with the opposing party’s written consent or the court’s leave.” Fed. R. Civ. P. 15(a)(2). Rule 15(a)(2) states that “[t]he court should freely give leave when justice so requires,” but “parties do not have an absolute right to amend their pleadings, even under this liberal standard.” *Sherman v. Winco Fireworks, Inc.*, 532 F.3d 709, 715 (8th Cir. 2008) (internal citation omitted). “A district court appropriately denies the movant leave to amend if there are compelling reasons such as undue delay, bad faith, or dilatory motive, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the non-moving party, or futility of the amendment.” *Id.* (internal quotations and citation omitted). A proposed amendment is futile where the court concludes that the newly-pled claim could not survive a motion to dismiss under Fed. R. Civ. P. 12(b)(6). *Cornelia I. Crowell GST Trust v. Possis Med., Inc.*, 519 F.3d 778, 784 (8th Cir. 2008). That said, “the Eighth Circuit has been clear that a district court should be reluctant to deny a motion to amend based on the merits of the asserted claim or defense,” and that denial based on futility should therefore only occur where the amendments assert “clearly frivolous claims or defenses.” *See Monsanto Co. v. Genesis AG, Ltd.*, 2007 WL 45789, at \*2 (E.D. Mo. 2007) (citing *Becker v. Univ. of Nebraska at Omaha*, 191 F.3d 904, 908 (8th Cir. 1999); *Gamma-10 Plastics, Inc. v. Am. President Lines, Ltd.*, 32 F.3d 1244, 1255 (8th Cir. 1994)).

Defendants seek leave to file a Second Amended Answer and Counterclaims (“SAAC”), which according to Defendants responds to Monsanto’s requests for more information on

Defendants' counterclaims and therefore includes amendments to: (1) inequitable conduct and fraud allegations; (2) antitrust "switching strategy" allegations; (3) patent unenforceability and affirmative antitrust allegations; (4) claims and defenses requesting contract reformation; and (5) newly-pled affirmative defenses asserting the 35 U.S.C. § 271(e)(1) safe harbor and the common-law experimental use exemption to claims of patent infringement, judicial estoppel, and preemption. Monsanto does not object to the SAAC *in toto*; instead, Monsanto contends only that all amendments or new allegations related to reformation are impermissible based on the Court's January 15 Order, and that the safe harbor and experimental use affirmative defenses should be denied on grounds of futility. As such, the Court concludes that Defendants' timely Motion will be granted with respect to those amendments to which Monsanto does not object, and the Court considers Monsanto's objections to the reformation-related amendments, the § 271(e)(1) safe harbor defense, and the common-law experimental use exemption in turn.

**A. Claims and Defenses Seeking Reformation**

The SAAC contains the following amendments with respect to reformation: (1) a repleading of their Counterclaim XI, for a declaratory judgment that Defendants did not breach the soybean or corn license agreements, either because their actions did not constitute a breach or because the agreements must be reformed; (2) a counterclaim for reformation due to mutual mistake; (3) a counterclaim for reformation due to Defendants' unilateral mistake and Monsanto's knowing silence; (4) a counterclaim for reformation due to Monsanto's fraudulent misrepresentation as to the legal effect of the license agreements; and (5) a repleading of their reformation defense, asserting the grounds for reformation in the aforementioned reformation counterclaims. Monsanto claims that these amendments should not be permitted because these

claims are futile, primarily due to the “Entire Agreement,” or integration, clause and the “No Other Warranties” clause in the license agreements.<sup>2</sup>

Reformation is an equitable remedy under which a court may reform a contract “in order to express the ‘real agreement’ of the parties involved.” *Cerberus Int’l, Ltd. v. Apollo Mgmt., L.P.*, 794 A.2d 1141, 1151 (Del. 2002). Delaware recognizes three grounds for reformation claims: mutual mistake, unilateral mistake coupled with knowing silence of the other party, and fraud. *See id.* at 1151 (mutual and unilateral mistake); *Emmert v. Prade*, 711 A.2d 1217, 1219 (Del. Ch. 1997) (fraud). Under all of these theories, the party seeking reformation must demonstrate by clear and convincing evidence “that the parties came to a specific prior understanding that differed materially from the written agreement.” *Cerberus*, 794 A.2d at 1151-52.

There is Delaware authority suggesting that claims of fraud or mistake based on extra-contractual representations are barred where the contract contains an integration clause. *See, e.g., Progressive Int’l Corp. v. E.I. DuPont de Nemours & Co.*, 2002 WL 1558382, at \*7 (Del. Ch. 2002) (concluding that the plaintiff had, as a matter of law, failed to state claims for fraud and mutual mistake, because “[a]bsent fraud or other unconscionable circumstances . . . , the existence of an integration clause between sophisticated parties is conclusive evidence that the parties intended the written contract to be their complete agreement.”); *Great Lakes Chem. Corp. v. Pharmacia Corp.*, 788 A.2d 544, 556 (Del. Ch. 2001) (“Were this Court to allow Great Lakes to disregard the clear terms of its disclaimers and to assert its claims of fraud, the carefully

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<sup>2</sup> Monsanto also contends that these amendments should be denied because the Court already rejected Defendants’ reformation claims based on its dismissal of Defendants’ Counterclaim XI in the January 15 Order, but as set forth above in Section I, the Court has reconsidered its dismissal of that claim.

negotiated and crafted Purchase Agreement between the parties . . . would not be worth the paper it is written on.”); *H-M Wexford LLC v. Encorp, Inc.*, 832 A.2d 129, 141-42 (Del. Ch. 2003) (representations in memorandum containing financial information could not serve as basis for breach of contract claim because integration clause precluded reliance on any representation or warranty not referenced therein). Defendants correctly note, however, that Delaware courts have, in certain instances, permitted fraud and misrepresentation claims premised on extra-contractual representations or understandings to go forward where the clause is essentially boilerplate. *See, e.g., Kronenberg v. Katz*, 872 A.2d 568, 592-94 (Del. Ch. 2004) (“The presence of a standard integration clause alone, which does not contain explicit anti-reliance representations and which is not accompanied by other contractual provisions demonstrating with clarity that the plaintiff had agreed that it was not relying on facts outside the contract, will not suffice to bar fraud claims.”); *Norton v. Poplos*, 443 A.2d 1, 6 (Del. 1982) (“[E]ven if a sales contract contains a merger clause, a buyer may rescind the contract if it resulted from an innocent but material misrepresentation by a seller.”).

These latter cases make clear that although it will be difficult for Defendants to prove their reformation claims, especially given the clear and convincing evidence standard, it would be improper to deny leave to amend on grounds of futility because these claims are not “clearly frivolous.” *See Gamma-10 Plastics, Inc. v. Am. President Lines, LTD.*, 32 F.3d 1244, 1255 (8th Cir. 1994). Notably, Monsanto’s principal case on this point, *Progressive*, holding that “the existence of an integration clause between sophisticated parties is conclusive evidence that the parties intended the written contract to be their complete agreement,” 2002 WL 1558382, at \*7, was authored by Vice Chancellor Strine, who is also responsible for *Katz*, in which the court concluded that a boilerplate clause is insufficient to bar fraud claims because “the intent to

preclude reliance on extra-contractual statements must emerge clearly and unambiguously from the contract.” 872 A.2d at 593. Both cases involve contracts between sophisticated parties, and as such, *Katz* can reasonably be read as a retreat from *Progressive*’s broad holding concerning the effect of integration clauses in such circumstances.<sup>3</sup>

In this case, perhaps even more so than in *Katz*, the integration clause claimed to bar Defendants’ allegations of fraud and mistake is undoubtedly boilerplate: “This Agreement constitutes the entire agreement between the parties regarding the subject matter hereof and all prior negotiations and understandings between the parties shall be deemed merged in this Agreement.” Defendants therefore have, at the very least, a colorable argument under *Katz* that the clause should not bar their reformation claims. Monsanto also posits that the “No Other Warranties” clause should bar these claims, but that clause could also plausibly be read to support Defendants’ grounds for reformation. It provides a number of subjects about which Monsanto makes no representations or warranties outside of the text of the agreements, including defined terms such as “Licensed Commercial Seed” and “Monsanto Patent Rights,” but it does not refer to the scope of the license grant or the “Licensed Field” stacking restriction – the subjects of the claimed misrepresentations or prior understandings.

The Court therefore concludes that Defendants will be granted leave to amend to assert these additional reformation-related claims and defenses, as Defendants have sufficiently demonstrated that they are not “clearly frivolous.”

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<sup>3</sup> The Court is also inclined to believe that an integration clause should not, as a logical matter, have any effect on a claim of mutual mistake, but that is not a basis for the Court’s ultimate conclusion on whether to grant leave to amend.

## **B. Safe Harbor Affirmative Defense**

Defendants' proposed amendment adding the safe harbor affirmative defense is based on 35 U.S.C. § 271(e)(1), which provides that "[i]t shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products." In interpreting this provision, the Supreme Court has concluded that it is "apparent from the statutory text that § 271(e)(1)'s exemption from infringement extends to all uses of patented inventions that are reasonably related to the development and submission of any information under the [Federal Food, Drug, and Cosmetic Act ("FDCA")].” *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 202 (2005) (internal citation omitted).

Monsanto argues that it would be futile for Defendants to assert this affirmative defense because the safe harbor only applies to “patented inventions” that are subject to pre-market approval, such as drugs and medical devices. According to Monsanto, the FDA does not require pre-market approval for genetically-modified soybean and corn seed products because they are “generally regarded as safe,” *see* Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22984-01 (May 29, 1992), and as such, Defendants' allegedly infringing use of Monsanto's patented RR traits is not “reasonably related” to a submission for regulatory approval under federal law.

The Court agrees with Defendants, however, that a lack of a pre-market approval requirement does not necessarily mean that the safe harbor is inapplicable. Defendants assert that irrespective of what the FDA *requires* at this point in time, virtually every manufacturer of genetically-modified seed products, including Monsanto and Defendants, does submit information



about its products to the FDA, in accordance with the FDCA's consultation process. Using the patented technology to assemble information for such consultation submissions is, at the very least, arguably "reasonably related" to submissions "of any information under the FDCA," *see Integra Lifesciences I*, 545 U.S. at 202, and the limited briefing of this issue makes the Court unwilling to reach a contrary conclusion in the context of this Motion. To the extent pre-market approval is not required for these products, the Court is skeptical that Defendants' use of the RR traits could be considered to be "*solely* for uses reasonably related" to such submissions to the FDA, but that appears to be a factual issue that the Court is likewise unwilling to decide at this juncture. Accordingly, the Court finds that Defendants' assertion of this defense is not "clearly frivolous," and leave to amend will therefore be granted.

### **C. Experimental Use Affirmative Defense**

The experimental use defense to a charge of patent infringement is a "very narrow" and "strictly limited" exception, applicable only where the infringing use is "for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry." *Madey v. Duke Univ.*, 307 F.3d 1351, 1361-62 (Fed. Cir. 2002) (quoting *Embrex, Inc. v. Serv. Eng'g Corp.*, 216 F.3d 1343, 1349 (Fed. Cir. 2000) (internal quotations omitted)). "[U]se does not qualify for the experimental use defense when it is undertaken in the guise of scientific inquiry but has definite, cognizable, and not insubstantial commercial purposes." *Id.* at 1362 (internal quotations and citations omitted). Thus, "use is disqualified from the defense if it has the slightest commercial implication" or if it is "in keeping with the legitimate business of the alleged infringer." *Id.* (internal citation omitted).

Nevertheless, Defendants claim that the experimental use exemption allows them to use the RR trait "to understand it, or to improve upon it . . . or 'design around it.'" *See Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860, 875 (Fed. Cir. 2003) (Newman, J.,

dissenting), *rev'd*, 545 U.S. 193 (2005). Judge Newman's characterization of the defense is at odds with the majority's opinion, however, which makes clear that Judge Newman sought in dissent to voice her disagreement with *Madey*, and that the issue of the experimental use exemption was not before the court. *See id.* at 864 n.2 ("In her dissent, Judge Newman takes this opportunity to restate her dissatisfaction with this court's decision in [*Madey*]. However, the common law experimental use exception is not before the court in the instant case."). Applying *Madey*, the defense is plainly inapplicable in this case because Defendants' allegedly infringing use – their OGAT/RR stacked soybean and corn seed products – has commercial implications *and* is directly in line with their legitimate business operations in manufacturing seed products. Defendants have admitted that they intend to commercialize OGAT/RR soybeans, and even if they do not intend to do the same with OGAT/RR corn, commercial implications are irrelevant if the infringing acts are consistent with the defendant's business operations. *Id.* ("[O]ur precedent does not immunize any conduct that is in keeping with the alleged infringer's legitimate business, regardless of commercial implications."). Indeed, the *Madey* court concluded that Duke University could not assert the defense with respect to research activities "with arguably no commercial application whatsoever" because research projects further Duke's aims of "educating and enlightening students and faculty" and "increase the status of the institution and lure lucrative research grants, students and faculty." If a university's research projects do not qualify under the experimental use exemption, it is clear that the creation of genetically-modified seed products by corporations in the business of selling such products likewise does not qualify. As a result, the Court will not grant Defendants leave to amend to add this affirmative defense asserting the experimental use exemption.

#### **D. Conclusion**

Defendants' Motion for Leave to File Second Amended Answer and Counterclaims will be granted in part and denied in part. The majority of the proposed amendments will be permitted because Defendants' Motion is timely and is not opposed by Monsanto. Monsanto's objections notwithstanding, Defendants will also be permitted to amend their reformation-related claims and defenses, as well as assert an additional affirmative defense based on the 35 U.S.C. § 271(e) safe harbor, because Defendants have made a sufficient showing that these amendments are not clearly frivolous. Their proposed amendment asserting the experimental use exemption to patent infringement, however, will be denied on grounds of futility, as the defense is plainly inapplicable on the facts of this case.

#### **IV. MOTION TO CLARIFY MEMORANDUM AND ORDER**

This Motion arises out of a dispute between Defendants and Monsanto as to the import of the Court's September 16, 2009 Memorandum and Order ("the September 16 Order"). In that Order, the Court ordered a separate trial of Defendants' antitrust counterclaims, but concluded that discovery should proceed on Defendants' "switching strategy" antitrust allegations and an allegedly anticompetitive Monsanto-Dow agreement.

Monsanto contends that the Court's Order limits Defendants' discovery on the "switching strategy" to allegations that Monsanto is using new license agreements to coerce independent seed companies to switch directly from Monsanto's RR trait to its new Roundup Ready® 2 Yield trait, but the Court agrees with Defendants that this is an overly narrow reading of the Order. The Court did, in the interest of brevity, at one point characterize the "switching strategy" theory as such, but a full reading of the Order makes clear that the Court ordered discovery to proceed on the full scope of the "switching strategy" allegations as pled by Defendants. The license

agreements are one component of the alleged “switching strategy,” but as Defendants note, the purported overall strategy is also comprised of, among other things, allegedly anticompetitive restrictions on trait stacking, restrictions on change of control of seed companies, and co-branding restrictions. It is clear from Defendants’ pleadings, and from their representations to the Court both at the hearing on this Motion and at the hearing that resulted in the September 16 Order, that Defendants also view these other licensing practices as necessary components of the “switching strategy.”

Defendants assert that these licensing practices, when viewed in concert and in the context of monopoly power, violate § 2 of the Sherman Act, even if they might be permissible if analyzed individually. As such, the Court concluded that resolution of Monsanto’s contract and patent claims would not moot the “switching strategy” allegations, and there was therefore no reason to prohibit Defendants from proceeding with discovery on those allegations. In contrast, the Court stayed discovery on those antitrust claims that depended on, or could in some way be affected by, resolution of Monsanto’s patent claims – those alleging patent fraud, sham litigation to enforce those patents, and misrepresentations concerning Monsanto’s patent position.

The Court is not unmindful of Defendants’ position that the Court’s decision to bifurcate to allow for a trial on Monsanto’s patent infringement and breach of contract claims may be detrimental to Defendants, because Monsanto will be implementing the alleged “switching strategy” while the patent infringement and breach of contract case is proceeding to resolution. The Court fully expects that all phases of discovery related to the “switching strategy” should proceed so that the Court can expeditiously move to resolve all remaining issues, understanding the parties will have already progressed in completing discovery on the “switching strategy.” The

Court emphasizes, however, that it will not permit these issues to be considered in the patent infringement / breach of contract trial.

As such, the Court finds that Defendants' Motion will be granted, to the extent it requests an order permitting them to proceed with discovery on the full scope of their "switching strategy" allegations. Because these allegations, at least in theory, remain viable irrespective of the outcome of Monsanto's patent and contract claims, Defendants are entitled, pursuant to the September 16 Order, to proceed with discovery on the full scope of the "switching strategy" allegations set forth in their SAAC.<sup>4</sup>

Accordingly,

**IT IS HEREBY ORDERED** that Defendants' Motion for Reconsideration [doc. #147] is **GRANTED, in part** and **DENIED, in part**. The Court reconsiders (1) its finding of implied negative covenants in the license agreements between Monsanto and Defendants, (2) its finding that Defendants breached those implied covenants, and (3) its corresponding dismissal of Defendants' Counterclaim XI, and the Court's January 15, 2010 Memorandum and Order is vacated to the extent it is inconsistent with this Order. Defendants' Motion is otherwise denied.

**IT IS FURTHER ORDERED** that Defendants' Motion for Certification of Questions of Law to the Delaware Supreme Court [doc. #153] is **DENIED**.

**IT IS FURTHER ORDERED** that Defendants' Motion for Leave to File Second Amended Answer and Counterclaims [doc. #162] is **GRANTED, in part** and **DENIED, in part**. Defendants' Motion is denied with respect to their proposed affirmative defense based on the experimental use exemption to patent infringement, and is otherwise granted. Defendants shall

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<sup>4</sup>As discussed above, Monsanto did not oppose Defendants' request for leave to amend their "switching strategy" allegations.

file their Second Amended Answer and Counterclaims no later than **August 20, 2010**, and Monsanto shall file its Answer thereto no later than **September 10, 2010**.

**IT IS FURTHER ORDERED** that pursuant to the Court's grant of leave to Defendants to file their Second Amended Answer and Counterclaims, which includes amendments to Defendants' inequitable conduct allegations, Monsanto's Motion to Dismiss Defendants' Inequitable Conduct Counterclaim [doc. #80] is **DENIED, as moot**, with leave to re-file.

**IT IS FURTHER ORDERED** that Defendants' Motion to Clarify Memorandum and Order [doc. #192] is **GRANTED**. Defendants shall be entitled to proceed with discovery on the full scope of their "switching strategy" antitrust allegations, as set forth in their Second Amended Answer and Counterclaims.

Dated this 30th Day of July, 2010.

  
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E. RICHARD WEBBER  
UNITED STATES DISTRICT JUDGE